

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO.

TRANSMITTAL LETTER TO THE UNITED STATES

DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A FILING UNDER 35 USC 371 AND 37 CFR 1.491

213653

U.S. APPLICATION NO.

09/937941

INTERNATIONAL APPLICATION NO.

PCT/EP00/02953

INTERNATIONAL FILING DATE

3 April 2000

PRIORITY DATE CLAIMED

8 April 1999

TITLE OF INVENTION

IMPROVED BONE SCREW FOR USE IN ORTHOPAEDIC SURGERY

APPLICANT(S) FOR DO/EO/US

Daniele Venturini

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 USC 371 and 37 CFR 1.491.
3. ☒ This is an express request to begin national examination procedures (35 USC 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 USC 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 USC 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)).
9. ☒ An unexecuted oath or declaration of the inventor(s) (35 USC 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)).
11. Nucleotide and/or Amino Acid Sequence Submission
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ Paper Copy
 - c. ☐ Statement verifying identity of above copies

Items 12 to 19 below concern other document(s) or information included:

12. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
 - ☒ Form PTO-1449
 - ☒ Copies of Listed Documents
13. ☐ An assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☐ A FIRST preliminary amendment.
- ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☒ Application Data Sheet Under 37 CFR 1.76
18. ☒ Return Receipt Postcard
19. ☐ Other items or information:

APPLICATION NO. <div style="font-size: 1.5em; font-weight: bold; margin-top: 5px;">09/937941</div>	INTERNATIONAL APPLICATION NO. PCT/EP00/02953	ATTORNEY DOCKET NO. 213653
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20. ☒ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY																				
Basic National Fee (37 CFR 1.492(a)(1)-(5)):																						
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	\$1,000.00																					
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	\$ 860.00																					
International preliminary examination fee (37 CFR 1.482) not paid to USPTO, but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	\$ 710.00																					
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	\$ 690.00																					
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1) to (4)	\$ 100.00																					
ENTER APPROPRIATE BASIC FEE AMOUNT=	\$860.00																					
Surcharge of \$130.00 for furnishing the National fee or oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date	\$0.00																					
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">CLAIMS</th> <th style="width: 15%;">NUMBER FILED</th> <th style="width: 15%;">NUMBER EXTRA</th> <th style="width: 15%;">RATE</th> <th style="width: 40%;"></th> </tr> </thead> <tbody> <tr> <td>Total Claims</td> <td>10</td> <td>-20=</td> <td>0</td> <td>x \$ 18.00</td> </tr> <tr> <td>Independent Claims</td> <td>1</td> <td>- 3 =</td> <td>0</td> <td>x \$ 80.00</td> </tr> <tr> <td colspan="4"><input type="checkbox"/> Multiple Dependent Claim(s) (if applicable)</td> <td>+ \$270.00</td> </tr> </tbody> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		Total Claims	10	-20=	0	x \$ 18.00	Independent Claims	1	- 3 =	0	x \$ 80.00	<input type="checkbox"/> Multiple Dependent Claim(s) (if applicable)				+ \$270.00		
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Independent Claims	1	- 3 =	0	x \$ 80.00																		
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TOTAL OF ABOVE CALCULATIONS=	\$860.00																					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.	\$0.00																					
SUBTOTAL=	\$860.00																					
Processing fee of \$130.00 for furnishing English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date.	\$0.00																					
TOTAL NATIONAL FEE=	\$860.00																					
Fee for recording the enclosed assignment. The assignment must be accompanied by an appropriate cover sheet. \$40.00 per property	+	\$0.00																				
TOTAL FEE ENCLOSED=	\$860.00																					
	Amount to be refunded	\$																				
	charged:	\$																				

a. ☒ A check in the amount of \$860.00 to cover the above fee is enclosed.


b. ☐ Please charge Deposit Account No. 12-1216 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

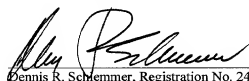
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PATENT TRADEMARK OFFICE



Dennis R. Schlemmer, Registration No. 24,703
One of the Attorneys for Applicant(s)

Date: October 2, 2001

PTO/PCT Rec'd 02 OCT 2001

- 1 -

Improved bone screw for use in orthopaedic surgery**DESCRIPTION****Technical Field**

This invention relates to an improved bone screw for use in orthopaedic surgery, specifically in devices for the external fixation of bone fractures.

More particularly, the invention relates to a screw having a head or application end, a shank, and a threaded portion, which tapers towards a tip at the opposite end from the application end.

Background Art

As is well known, a variety of external fixation devices are currently employed with increasing frequency in human as well as veterinary orthopaedic surgical procedures for treating complex fractures and/or fractures associated with serious damage to the cutaneous tissue.

Devices of this kind allow broken bones to be consolidated and reduced in highly critical areas of the human bony structure, especially near joints.

Customarily, the opposite ends of an external fixation device are secured to respective undamaged portions of a broken bone by means of bone screws set in the bone itself. Such is the case, for example, with a tibial fixation device having opposite ends firmly secured across the fracture to the shinbone.

In other cases, such as when the fracture affects a joint, the bone screws are set in bones adjacent to the joint. This is done, for example, with an ankle external fixation device by setting the bone screws in the tibia and the talus.

The effectiveness of such devices improves with the holding power of their bone screws. In some cases, the screws extend transversely through the bone to affect entrance and exit cortical regions.

A comprehensive literature exists in this specific technical field on research work directed to determine the critical parameters that control the holding power of bone screws.

As an example, it has been found that a relatively fine thread improves the holding power of the screw, as described in an article "Cortical profile external fixation screw maintains torque in the metaphysis", Anatomy, Bristol, June 17, 1996.

A radial preload on the screw prevents or attenuates the problem of

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the loss of grip or lysis in the first and/or the second cortical portion of the bone, as described in an article "Introduction and prevention of pin loosening in external fixation", Journal of Orthopaedic Trauma, Vol. 5, No. 4, pages 485-492.

Furthermore, providing a hole in the bone prior to inserting the screw, according to the screw diameter, lowers the insertion temperature which, if excessively high, can hurt the particular bone connective tissue around the screw, as described in an article "Cancellous Bone Screw Thread Design and Holding Power", Journal of Orthopaedic Trauma, Vol. 10, No. 7, pages 462-469.

The foregoing considerations lead to conclude that the holding power of a bone screw may be dependent on a series of features having a synergic combined effect.

However, application studies carried out at the Applicant's have resulted in the thread profile being identified as the fundamental factor of the screw holding power in the bone.

In particular, it has been found that conventional thread profiles have a common drawback in that they only provide an inferior distribution of the stress from the force applied to penetrate the cortical portion of the bone.

In addition, conventional bone screws are of greater bulk for a given area of bone interface.

The underlying technical problem of this invention is to provide an improved bone screw having such structural and functional features as to effectively produce a self-tapping penetrative action during its insertion in the bone, and exhibiting improved holding power once in place, thereby overcoming all the drawbacks discussed hereinabove in connection with the prior art.

Disclosure of Invention

The concept of this invention is one of providing a bone screw with a self-tapping threaded portion which includes at least one constant pitch section comprised of threads having a triangular cusp profile in cross-section and being separated from each other by a shaped bottom land with a concave profile defined by two countersloping planes. This allows the elongate conical profile of the threaded portion to be put to best use, and affords a large area of contact with the bone effective to reduce the specific loading pressure.

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Based on this concept, the technical problem is solved by a bone screw as previously indicated and defined in the characterising portions of Claim 1 following.

The features and advantages of a bone screw according to the invention will be apparent from the following description of an embodiment thereof, given by way of non-limiting example with reference to the accompanying drawings.

Brief Description of Drawings

Figure 1 is a perspective view showing schematically a bone screw according to this invention.

Figure 2 is a schematic side elevation view of the screw shown in Figure 1.

Figure 3 shows schematically, drawn to an enlarged scale, a portion of the thread profile of the screw in Figure 1.

Figure 4 shows, drawn to a further enlarged scale, a detail of the thread profile of Figure 3.

Figures 5A and 5B are respective enlarged views showing schematically the tip end of the screw of Figure 1, as viewed from two different angles.

Figure 6 is an enlarged front view showing schematically the tip end of the screw in Figure 1.

Figure 7 is a schematic detail view of the head end of the screw in Figure 1.

Modes for carrying out the Invention

Referring to the drawing views, in particular to the example of Figure 1, generally and schematically shown at 1 is a bone screw according to this invention intended for use in human or animal orthopaedic surgery with devices for the external fixation of bone fractures.

The screw 1 has a tip end 2 adapted to be implanted by a surgeon into the cortical portion of a bone, and then driven in a threaded manner by means of a tool applied to a head end 3 of the screw.

The screw 1 comprises a shank 4 and a threaded portion 5 formed integral with the shank 4. The threaded portion 5 has an elongate conical shape and the same diameter as the shank 4 at its region adjoining the shank, to then taper slightly in the direction towards the tip end 2. The threaded portion 5 accounts for about one third of the screw overall length. However, another length ratio of the threaded portion 5 to the

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shank 4 could be chosen instead.

Advantageously, the screw is of the self-tapping type in that it is formed with a helical thread pattern which can be termed directional in the sense that it will retain its drive direction more effectively even when applied a high torque.

Figure 3 is an enlarged view of the profile of the threaded portion 5 according to the invention.

Advantageously, the threaded portion has at least a section formed with a constant pitch, preferably a 1.25mm pitch, and comprises threads 9 having a triangular profile in cross-section with a cusp or acute apex angle of 15° to 30°.

The facing walls of two adjacent threads form an acute angle α of conical convergence towards the longitudinal axis X of the screw. In the embodiment of Figure 4, this angle is preferably no more than 30°.

Advantageously, the bottom land of the threads is shaped with a concave cross-section 10 between adjacent threads 9, effective to ease the material flow and relieve bone stress during the screw penetration.

The concave 10 is defined by two countersloping planes forming in cross-section an obtuse angle β of conical convergence towards the longitudinal axis of the screw. This obtuse angle is in the 120° to 150° range, preferably of 150° in the embodiment of Figure 3.

The region between the inner walls and the bottom land of the threads 9 is radiused to a radius of 0.2mm.

The thread height is three fifths the pitch, i.e. 0.75mm. It is constant along the profile 5.

This thread allows the conical profile to be used at its best by concentrating the drag in the opposite direction to the driving/piercing direction.

By way of illustration only, the screw 1 may have an overall length of 175mm, inclusive of 60mm of threaded portion 5.

A variety of lengths may be contemplated to provide the surgeon with a range of bone screws to use according to necessity. For example, a suitable range might include screws with an overall length of 140mm, including 40mm of threaded portion; or screws 210mm long with a 70mm threaded portion; or screws 255mm long with a threaded portion of at least 80mm.

Where the screw is 175mm long, the shank diameter is preferably of

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6mm, same as the outside diameter of the threaded portion 5 at the shank 4. At the tip end 2, the outside diameter of the threaded portion becomes 4mm.

Accordingly, the core diameter of the threaded portion will be 4.5mm at the shank, and 2.5mm at the tip.

Advantageously, the tip 2 of the screw 1 is formed with a pair of oppositely located grooves 11, 12 cut by straight-line milling.

The grooves extend at a predetermined inclination angle ϕ with respect to the longitudinal axis of the screw 1, and interfere with an end section of the threaded portion 5 near the tip.

The inclination angle ϕ is preferably of 150°.

The provision of such a groove pair allows the screw to be readily started into a hole pre-drilled through the bone, but also allows the section of the threaded portion that adjoins the tip and has not been removed to interfere with the second cortical portion of the bone.

To complete this description, it should be added that an annular groove 15 is provided near the head 3 of the screw 1 to facilitate cutting off a portion of the screw as may ultimately be protruding from the fixation device.

The screw of this invention is applied in a known manner in the art, with the one difference that the bone is pre-drilled in order to provide a suitable radial pre-load and keep the insertion temperature low.

Tests were conducted at the Applicant's, and finite element (FEM) calculations carried out on prototypes of a bone screw having the previously described thread profile.

The calculations were carried out to evaluate the effect of the two different thread profiles on a cancellous bone matrix in three distinct loading situations:

- 1) screw/bone interference;
- 2) pull-out force;
- 3) simulated actual loading.

It should be noted that the analysis of the stresses induced in the bone is not of absolute value, because of the bone being no linear elastic material. Accordingly, the values from the FEM analysis only become meaningful on a comparative basis, and in particular when compared with those for conventional bone screws used as references.

Loading situation (1) arises from the insertion of a thread having a

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5mm diameter (average of the conical diameter of the screw 1) and a thread height of 0.75mm. This means that the core diameter of the threaded portion is 3.5mm. A thread such as this was inserted through a 3.2mm hole. Under these conditions, the screw is working at a so-called interference "i" given as: (screw core diameter - hole diameter)/2 = (3.5 - 3.2)/2 = 0.15mm.

Pull-out situation (2) applies to the threaded screw being subjected to a specific unit tension ($p=1 \text{ N/mm}^2 = 1 \text{ MPa}$) in order to investigate its effect on a bonded cancellous bone. This situation simulates the pull-out effect in the absence of screw/bone interference, that is, similar to bone lysis situations.

Actual loading situation (3) is given by the combination of the previous two situations. In particular, a loading situation was simulated at an interference $i=0.15\text{mm}$ and a specific pull-out force of 8.5 MPa.

Now, the results of the FEM analysis, which have been summarized herein not to overburden the rest of the description, show that the screw of this invention distributes the stress better than conventional screws.

Furthermore, the pattern of the highest compressive stress from the pulling out shows that the screw of this invention transfers the stress onto several threads, whereas with conventional screws a single thread is mostly involved.

Finally, the screw of this invention shows to have a better distributed compression even in the absence of interference, that is in situations of an oversize pre-drilled hole, lysis or osteoporosis.

Thus, the bone screw according to the invention does solve the technical problem, and affords a number of advantages, outstanding among which is the fact that the thread profile of the screw allows the bone stress to be optimised, both as a result of the large area of contact with the bone and of the possibility given to the bony material to relax into the concave root lands of the threads. This allows the specific pressure under loading and the torque for screw penetration to be smaller.

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CLAIMS

1. An improved bone screw for use in orthopaedic surgery, in particular with external fracture fixation devices, of the type which comprises a head (3), a shank (4), and a threaded portion (5) tapering towards a tip (2) at the opposite end from the head (3), wherein said threaded portion (5) has at least one constant pitch section comprising threads (9) with an acute angle or cusp-like triangular profile in cross-section, characterised in that said threads (9) are separated from each other by a shaped bottom land having a concave profile (10) defined by two countersloping planes.

2. A bone screw according to Claim 1, characterised in that said shaped bottom land has in cross-section an obtuse angle (β) of conical convergence towards the longitudinal axis of the screw.

3. A bone screw according to Claim 2, characterised in that said obtuse angle (β) is an angle of at least 150° .

4. A bone screw according to Claim 1, characterised in that said cusp forms an angle in the 15° to 30° range.

5. A bone screw according to Claim 1, characterised in that said constant pitch is of 1.25mm.

6. A bone screw according to Claim 1, characterised in that the facing walls of adjacent threads have in cross-section an acute angle (α) of conical convergence towards the longitudinal axis of the screw.

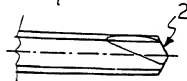
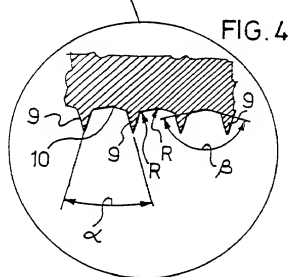
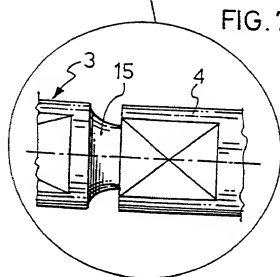
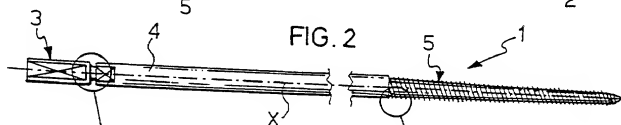
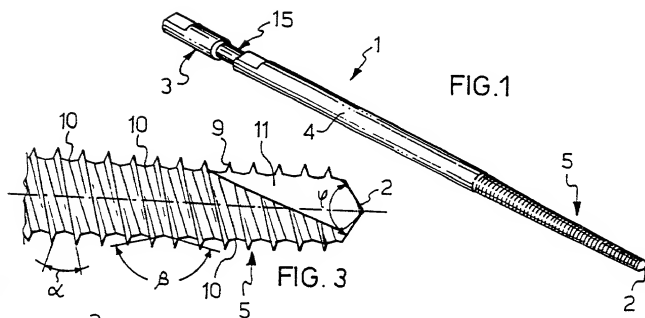
7. A bone screw according to Claim 6, characterised in that said acute angle (α) is an angle in the 15° to 30° range.

8. A bone screw according to Claim 1, characterised in that the threaded portion (5) accounts for about one third of the screw length.

9. A bone screw according to Claim 1, characterised in that the height of the thread is three fifths the pitch length.

10. A bone screw according to Claim 9, characterised in that said height is 0.75mm.

1/1



Declaration and Power of Attorney for Patent Application

Dichiarazione e procura ai fini della domanda di brevetto

Italian Language Declaration

Il sottoscritto inventore dichiara che:

La propria residenza, recapito postale e cittadinanza corrispondono a quanto indicato in calce, sotto la propria firma.

Ritiene di essere il primo ed unico inventore originale (se viene elencato in calce un solo nominativo) o il coinventore primo ed originale (se è elencato più di un nominativo) del oggetto rivendicato e per il quale il sottoscritto presenta domanda di brevetto. La invenzione in questione è chiamata

e la sua descrizione è allegata alla presente Dichiarazione a meno che non sia spuntata la seguente casella:

- ☐ Il _____
è stata depositata una domanda di brevetto
statunitense numero o una domanda di brevetto
internazionale PCT numero _____
che è stata modificata il _____
(se applicabile).

Il sottoscritto dichiara in oltre di aver letto e compreso il contenuto della descrizione identificata in precedenza, rivendicazioni comprese, come modificati dall'eventuale modifica summenzionata.

Il sottoscritto riconosce l'obbligo di rivelare informazioni essenziali ai fini della determinazione della brevettabilità ai sensi del Titolo 37, Codice dei Regolamenti Federali, § 1.56.

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

IMPROVED BONE SCREW FOR USE IN

ORTHOPAEDIC SURGERY

the specification of which is attached hereto unless the following box is checked:

- ☒ was filed on October 2, 2001
as United States Application Number or PCT
International Application Number
09/937,941 and was amended on
_____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

Italian Language Declaration

Il sottoscritto rivendica con la presente la priorità prevista dal Titolo 35, Codice degli Stati Uniti, § 119(e)-(d) o § 365(b) in relazione a qualsiasi domanda o domande estere di brevetto o certificato di inventore, o dal Titolo 35, § 365(a) degli stessi Codice in relazione a qualsiasi domanda internazionale PCT nella quale è designato almeno un paese diverso dagli Stati Uniti, i suddetti domande e certificati essendo elencati sotto, e, spuntando le seguenti caselle, ha anche identificato sotto qualsiasi domanda estera di brevetto o certificato di inventore, o domanda internazionale PCT, la cui data di deposito preceda quella della domanda per la quale è rivendicata la priorità.

Prior Foreign Application(s)

Domande Estere Anteriori
PCT/EP00/02953

WO

(Numero)

(Country)

(Numero)

(Nazione)

99830204.6

EP

(Numero)

(Country)

(Numero)

(Nazione)

Il sottoscritto rivendica con la presente i benefici previsti dal Titolo 35, Codici degli Stati Uniti, § 119(e), in relazione a qualsiasi domanda o domande provvisorie degli Stati Uniti elencate sotto.

(Application No.)

(Filing Date)

(N° della domanda)

(Data di deposito)

(Application No.)

(Filing Date)

(N° della domanda)

(Data di deposito)

Il sottoscritto rivendica con la presente i benefici previsti dal Titolo 35, Codice degli Stati Uniti, § 120, in relazione a qualsiasi domanda o domande statunitensi, o dal Titolo 35, § 365(c) degli stessi Codice in relazione a qualsiasi domanda internazionale PCT nella quale sono designati gli Stati Uniti, i suddette domande essendo elencate sotto e, nella misura in cui l'oggetto di ciascuna rivendicazione di questa domanda non sia stato esposto nella domanda statunitense o internazionale PCT anteriore nel modo previsto dal primo paragrafo del Titolo 35, Codice degli Stati Uniti, § 112, riconosce l'obbligo di rivelare informazioni essenziali ai fini della determinazione della brevettabilità ai sensi del Titolo 37, Codici dei Regolamenti Federali, § 1.56, le quali diventino disponibili durante il periodo compreso tra la data di deposito della domanda anteriore e la data di deposito nazionale o internazionale PCT della presente domanda.

(No.)

(Filing Date)

(N° della domanda)

(Data di deposito)

(Application No.)

(Filing Date)

(N° della domanda)

(Data di deposito)

Con la presente, il sottoscritto dichiara veritiera tutte le affermazioni contenute in questa domanda in relazione alle proprie conoscenze e di ritenere vere tutte le affermazioni o informazioni presentate. Dichiaro inoltre che tali asserzioni sono state espresse nella piena consapevolezza che le dichiarazioni intenzionalmente false sono punibili con una multa, l'incarcerazione o entrambe, ai sensi della Sezione 1001 del Titolo 18 del Codice degli Stati Uniti e che tali dichiarazioni intenzionalmente false possono mettere a repentaglio la validità della domanda o di qualsiasi brevetto rilasciato in merito.

I hereby claim foreign priority under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Priority Not Claimed

Diritto di priorità non rivendicato

3 April 2000

☐

(Day/Month/Year Filed)

(Giorno/Mese/Anno di deposito)

8 April 1999

☐

(Day/Month/Year Filed)

(Giorno/Mese/Anno di deposito)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(Status) (patented, pending, abandoned)

(Stato) (concessione di brevetto, in corso di esame, abbandono)

(Status) (patented, pending, abandoned)

(Stato) (concessione di brevetto, in corso di esame, abbandono)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Italian Language Declaration

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Nome e cognome dell'unico o del primo inventore	100	Full name of sole or first inventor	Daniele Venturini
Firma dell'inventore	Date	Inventor's signature	<i>[Signature]</i> Date Nov. 16, 2001
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Cittadinanza		Citizenship	Italy <i>ITX</i>
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Nome e cognome dell'eventuale secondo coinventore		Full name of second joint inventor, if any	
Firma del secondo coinventore	Date	Second Inventor's signature	Date
Residenza		Residence	
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Firma dell'inventore	Data	Inventor's signature	Date
Residenza		Residence	
Cittadinanza		Citizenship	
Recapito postale		Post Office Address	
Nome e cognome dell'eventuale secondo coinventore		Full name of fourth inventor	
Firma del secondo coinventore	Data	Second Inventor's signature	Date
Residenza		Residence	
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